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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,394	01/21/2000	Vanessa Hsei	P1085R6	5782

20995 7590 11/27/2001

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/27/2001

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,394

Applicant(s)

HSEI ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11,13,15,16,18-24 and 26-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration..
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,13,15,16,18-24 and 26-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 26 February 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. The request filed on 10/10/01 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/489,394 is acceptable and a RCE has been established. Claims 1-7, 9-11, 13, 15-16, 18-24, and 26-37 are pending and are currently under prosecution. An action on the RCE follows.
2. Claim 1 has been amended
Claims 1-7, 9-11, 13, 15-16, 18-24, and 26-37 are under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Information Disclosure Statement

4. The examiner acknowledges that copies of the IDS filed 2/26/01 will be forthcoming.

Rejection Withdrawn

5. The rejection of claims 1-7, 9-11, 13, 15-16, 18-24, 26-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claim

Response to Arguments

6. The rejection of claims 1-7, 9-11, 13, 15-16, 18-24, 26-37 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response filed 10/10/01 has been carefully considered but is deemed not to be persuasive. The response states that Haber teaches that "A and B chains recombine readily to form an active product even when the interchain disulfide bond is not permitted to form" (see page 3 of response) and "Tout presents no data or discussion relating to an antibody fragment lacking Cys128" (see page 4 of response) and "In fact, Haber teaches that the absence of an interchain disulfide bond between the H and L chains does not destroy stable association of the H and L chains or antigen-binding activity" (see page 4 of response). In response to these arguments, the arguments are not commensurate in scope with the claims. The claims recite an antibody that has a nonproteinaceous polymer covalently linked to a cysteine residue in either the light chain or the heavy chain. Although Haber may state that a disulfide bond is not needed for association, the claims require adding a nonproteinaceous polymer to the antibody and Haber teach fully reduced and carboxymethylation of the antibody led to inactivity (see page 1103) and specific conformation of the H and L chains are necessary for binding antigen. Meaning that covalent modification by adding even a small chemical moiety such as carboxymethyl resulted in no activity. Thus, one skill in the art would reasonable conclude that adding a larger molecule such as a 20kD or larger PEG moiety would not allow the H and L chains to associate and to be active.

There is no evidence in the specification or in the prior art of record to indicate that adding a nonproteinaceous polymer as large as 20Kd (or larger) to the cysteine in the H-L disulfide bond would result in a functioning antibody.

Thus, undue experimentation would be required to make and use the instantly claimed antibody fragments.

Conclusions

7. No Claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER